

REMARKS

Claims 1-14 are in this application. As will be explained in more detail below, claim 1 has been amended to define adjusting the pH of fermentation broth containing mevinolinic acid to 3.5 ± 0.1 . The other amendments to claim 1 will be discussed below.

According to the Office Action, claim 1 is rejected under 35 USC 112, second paragraph as being indefinite. This is respectfully traversed.

The Examiner states that the claim language regarding adjusting the pH of fermentation broth containing mevinolic acid at 3.5 ± 0.1 is unclear. It is respectfully requested that the Examiner refer to the flow chart included in the abstract and Figure 1 which clearly show that the mineral acid is added to the fermentation broth which results in the fermentation broth having a pH of 3.5 ± 0.1 . In addition, in the summary of the invention on page 7, lines 9-10 it is stated that the pH of the fermentation broth containing mevinolic acid (II) is adjusted to 3.5 ± 0.1 . Based on the above, part a) of claim 1 has been amended to read “ adjusting the pH of a fermentation broth containing mevinolinic acid(II) ~~at~~ to 3.5 ± 0.1 with a mineral acid.”

Claim 1 has also been amended so that the structure of mevinolic acid is included in step c) of the claim.

In step c) the letter “f” has been deleted.

The Examiner states that the use of the term “at” in line 1 of step c) is unclear. The applicants draw the Examiner’s attention to steps a) and b) of the process which are evidently carried out at room temperature and then the fermentation broth is heated at $55 \pm 5^{\circ}\text{C}$. In addition, the Examiner’s attention is drawn to Example 2, page 18, lines 3-5. Therefore, it is applicants’ position that the claim is clear.

It is applicants’ position that the terms pure and impure are understood by those of ordinary

skill in the art based on their knowledge and the disclosure of the specification. The Examiner's attention is drawn to page 5, lines 24-28; page 7, lines 2-3; scheme 1; and page 16, line 22 to the end of table 2 on page 17 of this specification. In addition, claim 1 includes the phrase "substantially free from impurities and conforming to pharmacopoeial specification." As the terms pure and impure are not indefinite, it is respectfully requested that this rejection be withdrawn.

Therefore, it is respectfully requested that the rejection under 35 USC 112 be withdrawn.

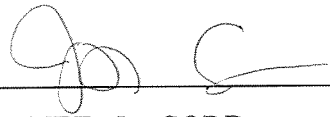
According to the Office Action, claims 1-14 are rejected under 35 USC 103(a) as being unpatentable over Kumar et al. (US Patent 7,052,886). This is respectfully traversed.

Although in column 4, lines 32-34, Kumar discloses lowering the pH of the fermented broth to 2.0 to 3.0, all of the examples disclose lactonization of mevinolinic acid at a pH of either 2.0; 2.1 or 2.2. It was found in carrying out this method that the result was a yield of only 54% of lovastatin. In contrast to this, applicants' claimed process wherein lactonization of mevolinic acid is at 3.5 ± 0.1 , results in a higher yield.

Therefore, it is respectfully requested that the rejection be withdrawn.

Accordingly, it is submitted that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Janet I. Cord', is written over a horizontal line.

JANET I. CORD

LADAS & PARRY LLP

26 WEST 61ST STREET

NEW YORK, NEW YORK 10023

REG.NO.33,778(212)708-1935